UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,650	05/09/2006	David B. Weiner	UPAP0020-100	2255

34137 7590 07/29/2008

Pepper Hamilton LLP
400 Berwyn Park
899 Cassatt Road
Berwyn, PA 19312-1183

EXAMINER	
SHEN, WU CHENG WINSTON	
ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
07/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,650	WEINER ET AL.	
	Examiner	Art Unit	
	WU-CHENG Winston SHEN	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,14-17,19,21-23,38 and 54-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,14-17,19,21-23,38 and 54-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/05/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Non-Final office action mailed on 07/16/2008 is vacated and replaced with this office action.

This application, 10/560,650, is a 371 of PCT/US04/18962 filed on 06/14/2004, which claims benefit of provisional application 60/478,205 filed on 06/13/2003 and claims benefit of provisional application 60/478,210 filed on 06/13/2003.

Election/Restrictions

1. Applicant's election of Group III, claims 1-6, 8, 9, 11, 14-17, 19-23, 29, 38, and 54 (each in part), drawn to an isolated nucleic acid molecule comprising a nucleic acid sequence consisting of: a nucleic acid sequence that encodes a fusion protein that consists of a *non-IgE protein sequences fused to a IgE signal peptide* that is from the same species as the non-IgE protein, a composition comprises the nucleic acid, a pharmaceutical composition comprises the nucleic acid, an recombinant vaccine comprises the nucleic acid, in the reply filed on 04/29/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1 and 16 are amended. Claims 2-13, 18, 20, 24-37, and 39-53 are cancelled. Claims 55-76 are newly added. Claims 1, 14-17, 19, 21-23, 38, and 54-76 are pending and currently under examination.

Claim Objection

2. Claims 1, 21, 22, 23, 55, 61-63, 73, and 74 are objected to because of the following informalities: (1) The phrase "a IgE signal peptide" recited in claims 1 and 55 is grammatically incorrect, which should read as "an IgE signal peptide"; (2) The phrase "An recombinant vaccine" recited in claims 22, 62, and 73 is grammatically incorrect, which should read "A recombinant vaccine"; (3) Claims 21 and 22 recite "the nucleic acid molecules of claim 1", however, claim 1 is limited to one of the two nucleic acid molecules; Therefore, claims 21 and 22 should recite "a nucleic acid molecule of claim 1" (4) Claims 61 and 62 recite "the nucleic acid molecules of claim 55", however, claim 55 depends from claim 1 and claim 1 is limited to one of the two recited nucleic acid molecules. Therefore, claims 61 and 62 should recite "a nucleic acid molecule of claim 1"; and (5) Claims 23, 63, and 74 recite "a recombinant vaccinia vaccine" and the phrase as written appears to be a vaccine whose intended use is for prevention of vaccinia virus infection. If that is not the case, it is advised to amend the phrase "a recombinant vaccinia vaccine" to "a recombinant vaccine comprising a vaccinia virus vector". Appropriate correction is required.

Information Disclosure Statement

3. The references cited starting from reference No: FD on page 11 to the reference No: KJ on page 23 of the IDS filed on 06/05/2008 are either GenBank accession numbers or Swissprot accession numbers. These references are not considered because the citation is incomplete as no date and/or version is provided. It is noted that the content of a given accession number of GenBank Database and Swissprot Database are subject to changes with time.

Scope of enablement

4. Claims 21-23, 54, 61-63, 65, 72-74, and 76 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising an isolated nucleic acid molecule, wherein the isolated nucleic acid molecule comprises a nucleic acid sequence consisting of a nucleic acid sequence that encodes a fusion protein that consists of either a non-IgE protein or an immuno-modulating protein sequence linked to an IgE signal peptide, **does not** reasonably provide enablement for (1) any pharmaceutical composition or (2) any DNA vaccine for generation of a protective immunity against the infection of a pathogen or against the development of a disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

It is noted that a vaccine is interpreted to be used for providing protective immunity. The claims are being examined to end for the purpose of the instant rejection.

The nature of the invention is directed to a composition comprising an isolated nucleic acid molecule for generation of an immune response in a subject, wherein upon administration of the nucleic acid that expresses a fusion protein consisting of an IgE signal/secretory peptide fused to a non-IgE protein or fused to an immuno-modulating protein, an immune response in the subject is induced. The specification discloses that the composition is intended for pharmaceutical use as a recombinant DNA vaccine. The breadth of the claims reads on any pharmaceutical composition and any recombinant DNA vaccine, wherein the pharmaceutical composition is used as a recombinant DNA vaccine and comprises an isolated nucleic acid molecule for generation of *any* immune response, including protective immunity in a subject against infection of a pathogen, or against the development of a cancer or an autoimmune disease, via administration of the nucleic acid that expresses a fusion protein consisting of an IgE signal/secretory peptide fused to a non-IgE protein or fused to an immuno-modulating protein.

The specification teaches IL-15 is a prototypic Th1 cytokine and an engineered IL-15 plasmid vaccine was constructed by removing the native IL-15 Kozak region, AUG's and UTRs, and the engineered IL-15 plasmid was provided with the coding sequence for IgE signal peptide. The engineered IL-15 was expressed at a level 30 to 50 times greater than that observed with a comparable wild type plasmid, and the immune response observed in mice co-immunized with engineered IgE signal-IL-15 and HIV-1 gag constructs were significantly greater than mice immunized with the HIV-1 gag construct alone (See Example 4, paragraphs [2004] and [213], and Figure 16, 2007/0041941, publication of instant application). This example demonstrates

the effect of expression of a cytokine such as IL-15 in enhancing the immune response elicited by the expression of HIV-1 gag.

With regard to the effect of expression of an antigen other than gag protein of HIV-1 in eliciting an immune response in the art, Yang et al 2001 disclosed a DNA vaccine encoding the West Nile Virus (WNV) capsid protein (Cp) was constructed, and the *in vivo* immune responses generated in DNA vaccine-immunized mice, and antigen-specific humoral (i.e. antibody mediated) and cellular (i.e. T-cell mediated) immune responses were observed, including a potent induction of antigen-specific (i.e. WNVCp-specific) Th1 and cytotoxic T lymphocyte responses, and dramatic infiltration of $CD4^+$ and $CD8^+$ T cells and macrophages also was observed at the muscle injection site. These results support the potential utility of this method as a tool for developing immunization strategies for WNV and other emerging pathogens (See abstract, Yang et al., Induction of potent Th1-type immune responses from a novel DNA vaccine for West Nile virus New York isolate (WNV-NY1999). *J Infect Dis.* 184(7):809-16, 2001).

However, it is noted that the specification and the art cited above do not provides enabling support regarding whether the immune response to HIV-1 gag protein or WNVCp protein can be long-lasting and effectively prevent the immunized subject from HIV or WNV infection. It is worth noting that the breadth of the claims reads on any DNA vaccine, for instance, a vaccine providing protective immunity against any pathogen infection, and a cancer vaccine providing protective immunity against processes of tumor development, and a vaccine providing protective immunity against any autoimmune disease. The specification does not provide any enabling support with regard to a vaccine providing protective immunity against any

pathogen infection, a vaccine providing protective immunity against any cancer development, and a vaccine providing protective immunity against any autoimmune disease.

In the art, the effectiveness of DNA vaccination as an approach for generation of protective immunity against a pathogen is unpredictable in general. For instance, **Belakova et al.** discusses critical factors affecting effectiveness of a DNA vaccine. These factors include (1) efficacious expression of protein DNA vaccine is dependent on the presence of DNA vaccine in the nucleus, and (2) the amount of actual protein synthesized in a DNA vaccine and effectiveness of the protein being presented to immune system as an antigen following DNA vaccination vary significantly (See last paragraph, left column, page 389, Belakova et al., DNA vaccines: are they still just a powerful tool for the future? *Arch Immunol Ther Exp (Warsz).* 55(6):387-98, 2007). Furthermore, Belakova et al. states that different routes of administration lead to marked different levels of protein expression as well as different levels of intensity and quality (Th1, Th2, antibody) of the immune response (See first paragraph, page 389, Belakova et al., 2007).

Directly related to instant application, with regard to the approach to enhance an immune response by the expression of a fusion protein, the status of art indicates the effect of fusion protein in eliciting an enhanced immune response for prevention of infection by a pathogen is unpredictable, because multiple factors/variations need to be considered. In this regard, Belakova et al. teaches heterologous antigen may play a role in modulating the immune response, the role may depend upon the nature of the antigen and/or the model system used (See bridging paragraph pages 393-394, Belakova et al., 2007), and the poor immune response to the majority of clinically tested DNA vaccines (See pages 394-395, Belakova et al., 2007).

Consistent with the unpredictabilities of DNA vaccination in general taught by Belakova et al., **Hu** discusses specific DNA vaccination in non-human primates (NHP) model in AIDS vaccine research. Hu teaches that a multitude of vaccines and immunization approaches have been evaluated, including DNA vaccines, and depending on the particular vaccine and model used, varying degrees of protection have been achieved, including prevention of infection, reduction of viral load, and amelioration of disease. Although sophisticated methodologies have been developed to define the mechanisms of protective immunity, a clear road map for HIV vaccine development, including DNA vaccine, has yet to emerge (See abstract, Hu, Non-human primate models for AIDS vaccine research. *Curr Drug Targets Infect Disord*. 5(2):193-201, 2005). Therefore, whether a protective immunity against HIV infection can be elicited in an individual by a DNA vaccine is unpredictable.

With regard to DNA cancer vaccine, consistent with the unpredictabilities of DNA vaccination in general taught by Belakova et al., **Mittendorf et al.** discusses, for instance, the search for breast cancer vaccines. Mittendorf et al. indicates that most of experimental DNA vaccines for preventing breast cancer have either not moved beyond preclinical testing or have not shown a significant clinical response. Mittendorf et al. teaches that prophylactic vaccines typically target infectious agents, but the evidence for an infectious etiology for breast cancer is largely descriptive and difficult to interpret. Mittendorf et al. teaches a strategy for a preventive breast cancer vaccine is to target tumor-associated antigens, and ongoing clinical trials are utilizing this approach, with preliminary results that are encouraging (See abstract, Mittendorf et al., Breast cancer vaccines: promise for the future or pipe dream? *Cancer*, 110(8):1677-86, 2007). Therefore, at the time of filing of instant application as well as at present, whether a

protective immunity against development of breast cancer can be elicited in an individual by a DNA vaccine remains unpredictable.

Consistent with the teachings of Belakova et al., Hu, and Mittendorf et al. discussed above, **Ulmer et al.** indicates that DNA vaccines have been widely used in efforts to develop vaccines against various pathogens as well as for cancer, autoimmune diseases and allergy. Ulmer et al. teaches DNA vaccines offer broad efficacy (particularly for their ability to generate both cellular and humoral immunity), ease of construction and manufacture and the potential for world-wide usage even in low-resource settings; however, despite their successful application in many preclinical disease models, their potency in human clinical trials has been insufficient to provide protective immunity (See abstract, Ulmer et al., Gene-based vaccines: recent technical and clinical advances. *Trends Mol Med.* 12(5):216-22, 2006).

In view of the state of the art, the unpredictability in the art, and the lack of specific guidance and working examples in the specification, one of skill in the art would have to perform undue experimentation to make and use the claimed invention commensurate in scope with the claims 21-23, 54, 61-63, 65, 72-74, and 76.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 14-17, 19, 21-23, 38, and 54-76 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Weiner et al. (US 2002/0123099, A1, Publication date Sep. 5, 2002).

Independent claim 1 is directed to an isolated nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of: a nucleic acid sequence that encodes a fusion protein that consists of a non-IgE protein sequences linked to an IgE signal peptide that is from the same species as the non-IgE protein; and a nucleic acid sequence that encodes a fusion protein that consists of a non-IgE protein sequences linked to an IgE signal peptide wherein the non-IgE protein is an immuno-modulating protein.

It is noted that the two inventors listed in the prior art Weiner et al. 2002 (David B. Weiner and Joo-Sung Yang) are also listed as the inventors of the four inventors listed in the instant application.

Weiner et al. teaches a secretory IgE signal leader sequence was fused to WNVC protein, which is the West Nile Virus (WNV) wild type capsid (Cp) protein. (See Figure 1, paragraph [0010]). Weiner et al. teaches an injectable pharmaceutical composition, a DNA vaccine, comprising a nucleic acid molecule that encodes a secretory IgE signal leader sequence was fused to WNVC protein, and the pharmaceutical composition/DNA vaccine is a plasmid or a recombinant vaccinia or adenoviral vector (See abstract, , paragraphs [0010]-[0013], [0071] and [0072], Weiner et al., 2002). Weiner et al. teaches WNCP is a non-IgE, immuno-modulating protein/immunogen that can be used to immunize an individual (See paragraphs [0081]-[0082],

claim 2, Weiner et al., 2002). These teachings by Weiner et al., 2002 read on claims 1, 14-17, 19, 21-23, 54-76.

In addition to West Nile Virus (WNV) wild type capsid (Cp) protein, Weiner et al. teaches the pharmaceutical composition comprises HIV-1 gag structural gene (See Example 4, Weiner et al., 2002), or nucleic acid encodes non-immunogenic therapeutic proteins including cytokines, growth factors, blood products, and enzymes (See paragraph [0010] and claim 47, Weiner et al., 2002). These teachings by Weiner et al., 2002 reads on claim 38.

Thus, Weiner et al. clearly anticipates claims 1, 14-17, 19, 21-23, 38, and 54-76 of instant application.

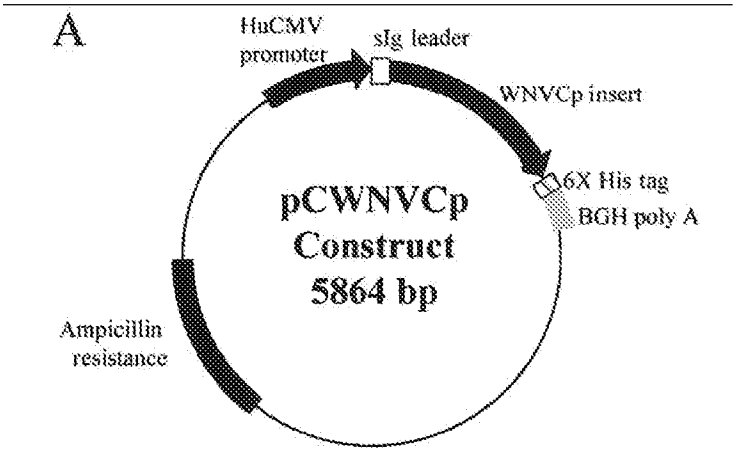
6. Claims 1, 14, 16, 17, 19, 21, 22, 38, 54-56, 58-62, 64-67, 69-73, 74 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al. (Yang et al., Induction of potent Th1-type immune responses from a novel DNA vaccine for West Nile virus New York isolate (WNV-NY1999). *J Infect Dis.* 184(7):809-16, 2001).

Independent claim 1 is directed to an isolated nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of: a nucleic acid sequence that encodes a fusion protein that consists of a non-IgE protein sequences linked to an IgE signal peptide that is from the same species as the non-IgE protein; and a nucleic acid sequence that encodes a fusion protein that consists of a non-IgE protein sequences linked to an IgE signal peptide wherein the non-IgE protein is an immuno-modulating protein.

Claim interpretation: In the absence any disclosed peptide sequence encoded by a nucleic acid sequence disclosed in specification and/or recited in the claims, the limitation "an IgE signal

peptide" is given the broadest and reasonable interpretation to encompass any variations of signal peptide of an immunoglobulin E. The limitation "and enzyme or functional fragment thereof" recited in claims 38, 64, and 75 reads on any fragment longer than 2 amino acid residues, including initiation codon Met, of any protein with any enzymatic activity, either by the fragment itself or by the association of the fragment with other enzyme(s).

Yang et al. teaches a recombinant DNA vaccine, a plasmid construct, as a pharmaceutical composition comprises a nucleic acid sequence encoding the human immunoglobulin secretory leader signal (See sIg leader, indicated in Figure 1A, Yang et al., 2001, and the plasmid map provided below) fused West Nile Virus (WNV) capsid protein (Cp). Yang et al. teaches that antigen-specific humoral and cellular immune response were observed in mice injected intramuscularly with the DNA vaccine construct (See abstract, Figure 1, Yang et al., 2001).



Thus, Yang et al., 2001 clearly anticipates claims 1, 14, 16, 17, 19, 21, 22, 38, 54-56, 58-62, 64-67, 69-73, 74 and 76 of instant application.

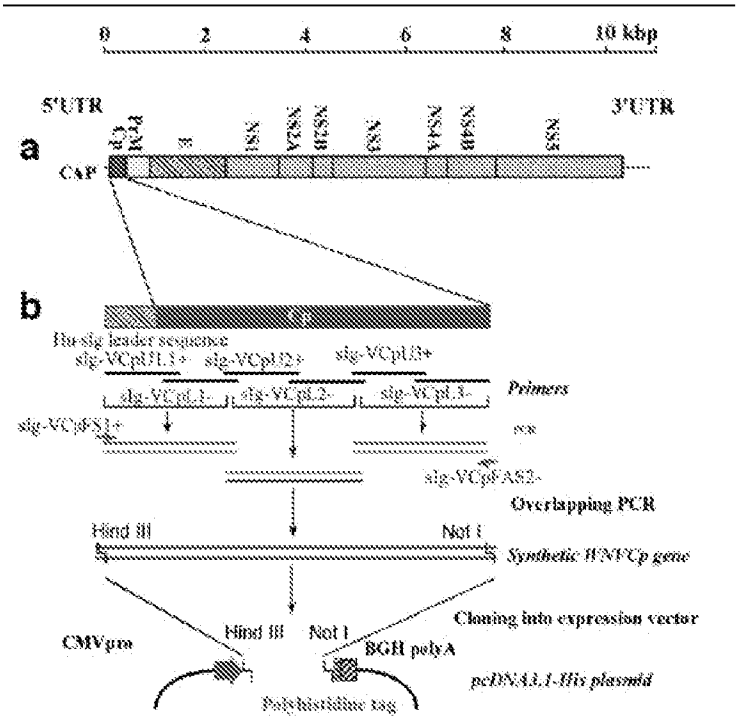
7. Claims 1, 14, 16, 17, 19, 21, 22, 38, 54-56, 58-62, 64-67, 69-73, 74 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al. (Yang et al., Induction of

inflammation by West Nile virus capsid through the caspase-9 apoptotic pathway. *Emerg Infect Dis*. 8(12):1379-84, 2002).

Independent claim 1 is directed to an isolated nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of: a nucleic acid sequence that encodes a fusion protein that consists of a non-IgE protein sequences linked to an IgE signal peptide that is from the same species as the non-IgE protein; and a nucleic acid sequence that encodes a fusion protein that consists of a non-IgE protein sequences linked to an IgE signal peptide wherein the non-IgE protein is an immuno-modulating protein.

Claim interpretation: In the absence any disclosed peptide sequence encoded by a nucleic acid sequence disclosed in specification and/or recited in the claims, the limitation "an IgE signal peptide" is given the broadest and reasonable interpretation to encompass any variations of signal peptide of an immunoglobulin E. The limitation "and enzyme or functional fragment thereof" recited in claims 38, 64, and 75 reads on any fragment longer than 2 amino acid residues, including initiation codon Met, of any protein with any enzymatic activity, either by the fragment itself or by the association of the fragment with other enzyme(s).

Yang et al. teaches a recombinant DNA vaccine, a plasmid construct, as a pharmaceutical composition comprises a nucleic acid sequence encoding the human immunoglobulin secretory leader signal (See abstract, Hu-sIg leader indicated in Figure 1b, Yang et al., 2002, and the plasmid map provided below) fused West Nile Virus (WNV) capsid protein (Cp).



Yang et al. teaches that induction of inflammation mediated by T-cell activation in mice directly injected with the DNA vaccine construct (See right column, page 1381, Yang et al., 2002).

Thus, Yang et al., 2002 clearly anticipates claims 1, 14, 16, 17, 19, 21, 22, 38, 54-56, 58-62, 64-67, 69-73, 74 and 76 of instant application.

Conclusion

8. No claim is allowed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Wu-Cheng Winston Shen whose telephone number is (571) 272-3157 and Fax number is 571-273-3157. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner, Peter Paras, can be reached on (571) 272-4517. The fax number for TC 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Wu-Cheng Winston Shen, Ph. D.
Patent Examiner
Art Unit 1632

/Peter Paras, Jr./

Supervisory Patent Examiner, Art Unit 1632